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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,389	12/10/2001	Vannie Kay Hodges	67,041-001	4900
26096 7590 12/19/2006 CARLSON, GASKEY & OLDS, P.C. 400 WEST MAPLE ROAD			EXAMINER	
			GLASS, RUSSELL S	
SUITE 350 BIRMINGHAN	л. MI 48009		ART UNIT	PAPER NUMBER
	,		3626	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVER	Y MODE
3 MONTHS		12/19/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

•		Application No.	Applicant(s)		
		10/016,389	HODGES, VANNIE KAY		
	Office Action Summary	Examiner	Art Unit		
		Russell S. Glass	3626		
	The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address		
Period for Reply					
WHIC - Exter after - If NO - Failur Any r	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE asions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory period verse to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).		
Status					
1)⊠	Responsive to communication(s) filed on <u>06 October 2006</u> .				
·—	This action is <b>FINAL</b> . 2b) This action is non-final.				
3) 🔲	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims		•		
4) Claim(s) 1-18 is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
-	Claim(s) <u>1-18</u> is/are rejected.				
	Claim(s) is/are objected to.	r alaction requirement			
8) Claim(s) are subject to restriction and/or election requirement.					
Applicati	on Papers				
9) The specification is objected to by the Examiner.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
' ')	The bath of declaration is objected to by the Ex	diffilier. Note the attached Office	Action of form F 10-132.		
Priority u	ınder 35 U.S.C. § 119	,			
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) All b) Some * c) None of:					
1. Certified copies of the priority documents have been received.					
<ul><li>2. Certified copies of the priority documents have been received in Application No</li><li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li></ul>					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
Attachmen		,			
1) Motice of References Cited (PTO-892) 4) Interview Summary (PTO-413) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date					
7) Notice of Dianaperson's Falcin Drawing Notice (170-152) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date 10/6/2006.  5) Notice of Informal Patent Application (PTO-152)  6) Other:					

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### **DETAILED ACTION**

# Requirement for Information Under 37 C.F.R. 1.105

1. Applicant has provided the information that the examiner has determined is reasonably necessary to the examination of this application. The information was provided in the IDS filed October 6, 2006.

### Claim Objections

2. The amendment to Claim 14 is noted and the objection is withdrawn.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1, 2, 5, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kay Hodges et al., *The Relationship Between The Child And Functional Assessment Scale (CAFAS) and Indicators of Functioning*, Journal of Child and Family Studies, Vol. 8, No. 1. 1999, pp. 109-122 ("Hodges")

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4. As per claim 1, Hodges discloses a method for grouping patients comprising the steps of:

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- 1) analyzing the patient and reaching an evaluation in each of several scales, (Hodges, p. 114,  $\P$  3-p. 115,  $\P$  1);
- 2) grouping an analyzed patient into one of several groups based upon an evaluation of the rankings in the scales, and utilizing a hierarchy for the scales to perform the grouping, (Hodges, p. 114, ¶ 3-p. 115, ¶ 1).
- 5. As per claim 2, Hodges discloses a method as set forth in claim 1, wherein the grouping of step 2 occurs by evaluating the rankings in a fashion such that if a particular scale is associated with a particularly severe ranking, then a grouping is made based upon the severe ranking, (Hodges, p. 114, ¶ 3-p. 115, ¶ 1).
- 6. As per claim 5, Hodges further discloses a method, wherein once a particular group has been identified for a patient, questions are asked with regard to the family or home of the patient to identify a recommended intensity of treatment, (Hodges, p. 11, ¶ 1).
- 7. As per claim 17, Hodges further discloses a method as set forth in Claim 1, wherein step 2 is performed by an individual other than a patient, (Hodges, p. 109, ¶ 1).

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8. As per claim 18, Hodges further discloses a wherein step 2 is performed by a healthcare professional, (Hodges, p. 109, ¶ 1).

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 3, 4, 6-16 are rejected under 35 U.S.C. 103(a) as being obvious in view of Kay Hodges et al., *The Relationship Between The Child And Functional Assessment Scale (CAFAS) and Indicators of Functioning*, Journal of Child and Family Studies, Vol. 8, No. 1. 1999, pp. 109-122 ("Hodges"), in view of McLeod, (U.S. 6,053,866).
- 10. As per claim 3, Hodges discloses a method, wherein a scale related to the ability to think is utilized as the scale to be evaluated, and if substantial problems are determined with regard to the thinking scale, then the patient is categorized with a group associated with thinking problems, (Hodges, p. 114, ¶ 3-p. 115, ¶ 1).

Hodges fails to disclose that thinking is evaluated first. However, it is well known in the art to first identify a preliminary disorder before moving on to an additional psychiatric disorder, (McLeod, Figure).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the CAFAS multidimensional impairment evaluation of Hodges into the psychiatric diagnosis system and method disclosed by McLeod. The motivation would have been to predict service utilization and cost of care, (McLeod, Abstract).

11. As per claim 4, Hodges further discloses a method wherein the scale evaluated is a substance use scale, and if the substance use scale has a particularly high ranking, then the patient is grouped into a substance use group, (Hodges, p. 114, ¶ 3-p. 115, ¶ 1).

Hodges fails to disclose that substance use is evaluated second. However, it is well known in the art to first identify a preliminary disorder before moving on to an additional psychiatric disorder, (McLeod, Figure).

The statement of obviousness and motivation to combine Hodges and McLeod is as provided in the rejection of claim 3 and incorporated herein by reference.

12. As per claim 6, McLeod discloses a tool for ranking patients comprising: a flowchart for evaluating scores in several scales, (McLeod, Abstract; Figure; col. 3, line 64-col. 5, line 25)(the workflow process disclosed is considered to be a flowchart),

said scales at least including a scale relating to a patient's ability to think, a patient's substance use history, and a patient's self-harmful behavior, said flowchart applying the scales in a hierarchy, and moving the patient into being placed in any one of a plurality of groups while moving through said hierarchy of scales, if a particular

scale is associated with a ranking above a particular value, (Hodges, p. 114,  $\P$  3-p. 115,  $\P$  1).

The statement of obviousness and motivation to combine Hodges and McLeod is as provided in the rejection of claim 3 and incorporated herein by reference.

- 13. As per claim 7, McLeod discloses a tool as recited in claim 6, wherein said flowchart is incorporated into a software program in a computer, (McLeod, Abstract; Figure; col. 5, lines 26-58).
- 14. As per claim 8, McLeod discloses a tool as recited in claim 6, wherein said flowchart is incorporated into paper form, (McLeod, Abstract; Figure; col. 5, lines 26-58).

The statement of obviousness and motivation to combine Hodges and McLeod is as provided in the rejection of claim 3 and incorporated herein by reference.

15. As per claim 9, Hodges discloses a tool as recited in claim 6, wherein additional questions are asked with regard to the family or home for the particular patient, based upon the identified group, and recommendations are made, in part, based upon the family or home of the patient, (Hodges, p. 111, ¶ 1).

The statement of obviousness and motivation to combine Hodges and McLeod is as provided in the rejection of claim 3 and incorporated herein by reference.

16. As per claim 10, Hodges discloses a tool as recited in claim 6, wherein once a

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group has been identified, further questions with regard to the patient's environment are asked to identify recommended care, (Hodges, p. 114, ¶ 3-p. 115, ¶ 1).

The statement of obviousness and motivation to combine Hodges and McLeod is as provided in the rejection of claim 3 and incorporated herein by reference.

- 17. As per claim 11, Hodges discloses a method of associating patients with a particular group comprising the steps of:
- 1) performing a CAFAS evaluation on a patient to identify scores in at least the thinking scale, the substance use scale and the self-harmful behavior scale, (Hodges, p. 114, ¶ 3-p. 115, ¶ 1);
- 2) evaluating the identified CAFAS scores, and if said thinking scale is above said particular value grouping the patient into a thinking tier, and if the thinking scale is below a particular value, asking whether the next score is above a particular value, (Hodges, p. 114, ¶ 3-p. 115, ¶ 1);
- 3) if the substance use score is above a particular value, grouping the patient into a substance use grouping, (Hodges, p. 114, ¶ 3-p. 115, ¶ 1); and
- 4) if the substance use score is below a particular value, next asking whether the self-harmful score is above a particular value, and grouping the patient into a self-harmful group, if the self-harmful group score is above a particular value, (Hodges, p. 114, ¶ 3-p. 115, ¶ 1).

Hodges fails to disclose a flowchart instructing that thinking is evaluated before substance abuse, which is evaluated before self-harmful. However, it is well known in

the art to first identify a preliminary disorder before moving on to an additional psychiatric disorder, (McLeod, Figure).

The statement of obviousness and motivation to combine Hodges and McLeod is as provided in the rejection of claim 3 and incorporated herein by reference.

18. As per claim 12, Hodges discloses a method as set forth in claim 11, wherein if a mood/emotion score is also above a particular value, grouping the patient into the self-harm group, (Hodges, p. 114, ¶ 3-p. 115, ¶ 1).

The statement of obviousness and motivation to combine Hodges and McLeod is as provided in the rejection of claim 3 and incorporated herein by reference.

19. As per claim 13, Hodges discloses a method as set forth in claim 11, wherein if both self-harmful and mood/emotion are below a particular value, next evaluating the patient's community score, and if the community score is above a particular value, grouping the patient into an uncomplicated delinquent group, (Hodges, p. 114, ¶ 3-p. 115, ¶ 1).

Hodges fails to disclose a flowchart instructing that self-harmful and moodemotion are evaluated before community. However, it is well known in the art to first identify a preliminary disorder before moving on to an additional psychiatric disorder, (McLeod, Figure).

The statement of obviousness and motivation to combine Hodges and McLeod is as provided in the rejection of claim 3 and incorporated herein by reference.

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20. As per claim 14, Hodges further discloses a method as set forth in claim 11, wherein once a particular group has been identified for a patient, questions are asked with regard to the family or home of the patient to identify a recommended intensity of treatment, (Hodges, p. 111, ¶ 1).

The statement of obviousness and motivation to combine Hodges and McLeod is as provided in the rejection of claim 3 and incorporated herein by reference.

21. A method as set forth in Claim 11, wherein the steps are performed by an individual other than the patient, (Hodges, p. 109, ¶ 1).

The statement of obviousness and motivation to combine Hodges and McLeod is as provided in the rejection of claim 3 and incorporated herein by reference.

22. A method as set forth in Claim 15, wherein the steps are performed by a healthcare professional, (Hodges, p. 109, ¶ 1).

The statement of obviousness and motivation to combine Hodges and McLeod is as provided in the rejection of claim 3 and incorporated herein by reference.

#### Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on October 6, 2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS** 

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MADE FINAL. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell S. Glass whose telephone number is 571-272-3132. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RSG 12/9/2006

> C. LUKE GILLIGAN AMON PATENT EXAMINER